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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/185,607	11/04/1998	SHUI-ON LEUNG	018733/0875	5589

7590 01/15/2003

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/185,607

Applicant(s)

LEUNG ET AL

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-19,21-38,40,41,43,44,46,47,49 and 53-55 is/are pending in the application.
- 4a) Of the above claim(s) 15,28 and 30-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-14, 16-19, 21-27, 29, 38, 41, 44, 46, 47, 49, 53-55 is/are rejected.
- 7) ☒ Claim(s) 2,40 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Request for Continued Examination

1. The request filed on 11/5/02 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/185,607 is acceptable and a RCE has been established. Claims 1-2, 4-19, 21-38, 40-41, 43-44, 46-47, 49, 53-55 are pending and claims 1, 4-14, 16-19, 21-27, 29, 38, 40-41, 43-44, 46-47, 49, 53-55 are currently under prosecution. An action on the RCE follows.
2. Claims 1, 6, 8, 16, 19, 22, 30, 38, 40, 41, 43, 44, 46, 47, 48, 53-55 have been amended. Claims 39, 42, 45, 48, and 50-52 have been cancelled.
3. Claims 15, 28, and 30-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made **without** traverse in Paper No. 12.
4. Claims 1-2, 4-14, 16-19, 21-27, 29, 38, 40-41, 43-44, 46-47, 49, 53-55 are under examination.
5. The text of those sections of Title 35, U.S.C. Code not included in this Office Action can be found in a prior Office Action.
6. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

7. The rejection of claims 39-40, 42-43, 45-46, 48-49, and 51-52 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in

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the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the amendments to the claims.

8. The rejection of claims 2, 19, 21-27, 29, 53-55 under 35 U.S.C. 112, first paragraph, is withdrawn.

Response to Arguments

9. The rejection of claims 1, 4-14, 16-18, 38, 41, 44, 47 under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 11/5/02 has been carefully considered but is deemed not to be persuasive. The response states that applicants contend that the skilled artisan would know there are very limited number of saccharides that would be used for glycosylation and Stryer showed formulas of saccharides and the examiners reference to "many" potential ketone derivatives is ill-founded and applicants have amended the claims to recite that the saccharide precursors are "biosynthetic" (see page 9 of response). In response to these arguments, while Stryer teaches saccharides, the claims recite a ketone derivative of a saccharide precursor which encompasses many formulas and compounds not just a saccharide as shown in Stryer. In addition, the claim recites "a ketone derivative of a saccharide" or "biosynthetic saccharide precursor" and not that the ketone derivative is a biosynthetic saccharide precursor. Therefore the

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claims still encompass a myriad of compounds and the specification only teaches two such compounds of N-levulinoyl mannosamine and N-levulinoyl fucose.

10. The rejection of claims 19, 21-27, 29 and 53-55 under 35 U.S.C. 103(a) as being unpatentable over Shih et al (U. S. Patent 5,057,313, issued 10/15/91) and further in view of Leung et al (int. J. Cancer 60:534-538, 1995, IDS #5) and Qu et al (Glycobiology 7:803-809, 9/97, IDS #5) is maintained.

The response filed 11/5/02 has been carefully considered but is deemed not to be persuasive. The response is summarized as the method relied upon for the rejection is based on harsh oxidation as opposed to the method of producing by the host cell's biosynthetic machinery and none of Leung, Qu, or Shih teach or suggest such a method (see page 6-9 of response). In response to these arguments, the rejected claims are to products that have a reactive ketone group on the glycosylated antibody and Shih teach this product. The claims have been amended to recite "wherein the reactive ketone group is not introduced by oxidation", however, because the claims are to products, it is immaterial how the product is made when the claims are directed to a product and there is no indication in the specification or the prior art that the structure of the reactive ketone would be different in the oxidized method vs the biosynthetic method.

Claim 55 is directed to an antibody prepared by the method of claim 1. Applicant is reminded that when the claim is directed to a product, the preamble is generally nonlimiting if the body of the claim is directed to an old composition and the preamble

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merely recites a property inherent in the old composition. [*Kropa v. Robie*, 88 USPQ 478, 480 - 81 (CCPA 1951); see also MPEP 2111.02.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

The following is a NEW GROUND of rejection

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 8-14, 16-18, 19, 21-27, 29, 44, 46, 47, 49, 53-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8, 16, 19, 22, 30, 44, 47, 53-55 have been amended to recite "wherein the reactive ketone group is not introduced by oxidation". The response filed 11/5/02 states that support for the amendment is found at page 2 of the specification and the response cites the teachings of Leung et al "Leung II" as support and the response states that the present invention provides glycosylated antibodies that do not require oxidation (see pages 6-7 of response). The response has been carefully considered but is deemed not to be persuasive. While the specification teaches a method that does not

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require oxidation the cited work by Leung II is just prior art and background and the specification does not show support for excluding oxidation of the sugar by chemical methods. Applicant is required to provide specific support for the limitation or remove it from the claims.

Conclusions

13. No Claims are allowed. Claims 2, 40, 43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

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Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, appearing to be 'L. Helms', written in a cursive style.